

EPA REGISTRATION NUMBER 81824-4
VOLUME 3



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 3, 2006


Michael Kellogg
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Amendment - Alternate Confidential Statement of Formula(s)
ENS-100
EPA Reg. No. 81824-4
Your Letter Dated: March 20, 2006

Dear Mr. Kellogg:

We have no objection to the use of the alternate formulation(s) (dated May 10, 2005) requested in your letter of the above date. The alternate confidential statements of formula is acceptable and has been inserted in the file for the subject product.

If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505P)

Date: July 3, 2006

SUBJECT: Product Chemistry Review of Bifenthrin Technical (ENS-100) TGAI / MUP

FROM: Shyam B. Mathur, Ph.D
Product Chemistry Team Leader
Technical Review Branch/RD (7505C)

S. B. Mathur
7/31/06
gm

TO: Be Wanda Alexander / George Larocca RM 13
Insecticide Branch / RD (7505C)

DP BARCODE: D328233

DECISION No.: 366193

File Symbol No.: 81824-4

PRODUCT: Bifenthrin (ENS-100)TGAI / MUP

PCC: 128825

REGISTRANT: Ensystex II, Incorporation

USE: Insecticide

INTRODUCTION:

The Pyxis Regulatory Consulting, Incorporation on behalf of the registrant Ensystex, Inc., has submitted an application for an alternate source of supply of ENS-100, a technical product containing bifenthrin as an active ingredient. The registrant has submitted a CSF for alternate formulation (dated 05-10-05) and the supporting product chemistry data for 830 series subgroup A, with MRID nos. 467880-01 & 467972-01. The ENS-100 is produced in Fayetteville, NC. TRB has been asked to evaluate the subgroup A product chemistry data submitted for the ENS-100.

SUMMARY OF FINDINGS:

1. The registrant has submitted a CSF for alternate formulation (dated 05-10-05) for ENS-100 TGAI / MUP, with a nominal concentration of 96.5% for the active ingredient bifenthrin. The proposed certified limits for the active ingredient are based on the standard certified limits set-forth in 40CFR§158.175(b)(2), where as the proposed certified limits for the impurities are based on the five batch analysis. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively [MRID No. 467880-01].

2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160 [MRID No. 467880-01].

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.162. The ENS-100 TGAI/MUP was manufactured in [REDACTED]. The details of the production process have been provided which included the amounts of each starting material used in the process, description of the equipment used, the reaction conditions (temperature, pH, etc.) and the yields of the final product and the steps taken to control the quality of the product. The manufacturing process utilized in NC produced bifenthrin (96.5%) containing cis-bifenthrin (> 97%) and trans-bifenthrin (< 3%)[MRID No. 467880-01].

Manufacturing process information may be entitled to confidential treatment

BARCODE: D328233; **Reg. No. :** 81824-4 **PRODUCT:** Bifenthrin (ENS-100) TGA/MUP

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.167. During the production of ENS-100 TGA/MUP [REDACTED] the registrant discussed and reported the formation of the [REDACTED] major impurities present at the levels of > 0.1% in addition to [REDACTED]. The registrant has provided discussion on the formation of these impurities and also discussed the theoretical possible impurities which can be produced during the course of the synthetic pathway. None of the impurities identified by the registrant are of toxicological significance as per discussion provided by the applicant [MRID No. 467880-01].

5. The data submitted corresponding the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.170. The study was conducted under GLP requirements in compliance with 40CFR§160. Five representative batches of the bifenthrin technical were analyzed for percent active ingredient and the impurities. The active ingredient (bifenthrin) content was determined by operating GC/MS in a full scan mode. One quantitation mass and two confirmation masses were selected for each analyte and internal standard. The impurity test for bifenthrin TGA/MUP were performed by GC/MS with electron impact ionization (EI). For two target impurity analytes, calibration was performed by using a five-point internal standard calibration. One another impurity was detected in bifenthrin technical in trace level by full scale analysis. The impurities were determined by operating the GC/MS in full scan mode. One quantitation mass and two confirmation masses were selected for each impurity analyte and internal standard [MRID No. 467972-01].

6. The data submitted corresponding the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The analytical method described above in Item #5 (GC/MS in full scan mode) can be used for the determination of the active ingredient bifenthrin in EN-100 TGA/MUP [MRID No 467972-01].

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for Bifenthrin Technical TGA / MUP and has concluded that:

1. The product chemistry data submitted corresponding to 830. 1550 (product identity & composition), 830.1600 (description of material used to produce the product), 830.1620 (description of production of the production process), 830.1670 (discussion on the formation of impurity), 830.1700 (preliminary analysis), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.155, 158.160, 158.162, 158.167, 158.170, 158.175, and 158.180 respectively and are acceptable.

2. The CSF for alternate formulation (dated 05-10-05) is acceptable.

BARCODE: D328233; **Reg. No. :** 81824-4 **PRODUCT:** Bifenthrin (ENS-100) TGAI/MUP

830.1550. Product identity & Composition: (MRID No. 467880-01)

Common Name: Bifenthrin

Chemical Name: CAS Name: (2-methyl [1, 1'-biphenyl]-3-yl)methyl-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-2,2-dimethylcyclopropanecarboxylate]

Chemical name: IUPAC name: 2-methylbiphenyl-3-ylmethyl (Z)3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate.

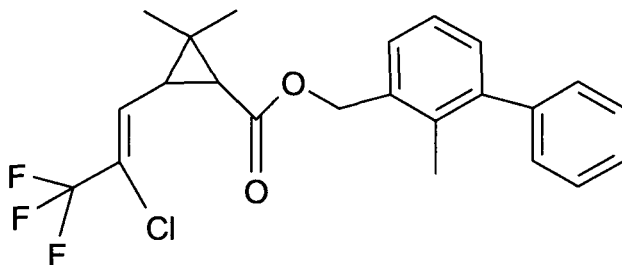
CAS No.: (Cis) 82657-04-3; (trans) 83322-02-5

PC Code No.: 128825

Empirical formula: $C_{23}H_{22}ClF_3O_2$

Molecular Weight: 422.9

Structural formula:



BARCODE: D328233; **Reg. No. :** 81824-4 **PRODUCT:** Bifenthrin (ENS-100) TGAI/MUP

Table 1. Manufacturing and Impurity Data for Bifenthrin (ENS-100) technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	Basic 05-10-05	A	The NC of AI (96.5%) is supported by 5 batch analysis and concurs with the label claim nominal concentration (96.5%).
830.1600	Description of materials used to produce the product	467880-01	A	MSDS's for starting materials have been submitted
830.1620	Description of production process	467880-01	A	██████████ has been described in details.
830.1670	Discussion of formation of impurities	467880-01	A	Discussions on the formation of ██████ major impurities have been provided. The mechanism & the origin of the formation of these impurities have been provided. No impurity of toxicological concern was identified in the discussion.
830.1700	Preliminary analysis	467972-01	A	The registrant has provided 5 batch analysis for the TGAI. The AI & impurities were identified and quantified by using GC/MS method. The methods were validated for accuracy, linearity, and precision. The five batch analysis supported the CSF for basic formulation.
830.1750	Certified limits	467972-01	A	The proposed certified limits for the AI are based on standard certified limits where as for the impurities are based on the five batch analyses.
830.1800	Enforcement analytical method	467972-01	A	The content of the Bifenthrin was determined by GC/MS method. The method was validated for accuracy, precision, and linearity.
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

Manufacturing process information may be entitled to confidential treatment

BARCODE: D328233; Reg. No. : 81824-4 PRODUCT: Bifenthrin (ENS-100) TGAI/MUP

830.1800. Enforcement Analytical method: (MRID No. 467972-01)

The purity test for bifenthrin TGAI were performed by gas chromatography/mass spectrometry on a Agilent 6890/5973 GC/MS with electron impact ionization and flame ionization detector (FID). Separation was performed on a 30 m x 0.25 mm i.d. ZB-5ms column. A volume of 1 µL of prepared sample solution was injected into a split/splitless injector maintained at 240 °C. The GC oven was programmed as follows: an initial temperature of 40 °C held for four minutes, then

a temperature ramp of 20 °C/minute to 310 °C, then held at 310 °C for four minutes. Each sample was analyzed at least twice.

The purity of bifenthrin TGAI samples were determined by operating the GC/MS in a full-scan mode. One quantitation mass and two confirmation masses were selected for each analyte and internal standard as follows:

<u>Analyte and Internal Standard</u>	<u>Masses Monitored</u>	<u>Quantitation Mass</u>
Phenanthrene-d10 (Internal standard)	80, 94, 188	188
Bifenthrin	166, 181, 165	166

The calibration was performed by using a five-point internal standard calibration method. Bifenthrin was quantified using phenanthrene-d10 as internal standard at a concentration of 10 ng/µL in the testing solution. Since commercial analytical standards of cis-bifenthrin and trans-bifenthrin are not available, the cis- and trans- isomers of bifenthrin were quantified respectively by total bifenthrin analytical standard assuming both isomers processing at the same reaction factor. To ensure better accuracy and less deviation, cis-bifenthrin was quantified by GC/FID that allowed more stable and better reproducibility than GC/MS for high percentage component.

C. Quantitation, Calculations and Statistical Methods

Calibration of the GC/MS was performed by injecting standard solutions containing analytes of interest at five different concentrations over the calibration range. Internal standard solution was added to each standard at the concentration of 10 µg/mL. Mean relative response factors were calculated using the equations provided in SwRI SOP GLP-01-14-10. The concentration of the target analyte in the sample was then determined by comparing the integrated area of the target analyte peak in selected ion chromatogram to that of the internal standard. The concentration (percent w/w) in the bifenthrin TGAI was then calculated by following equation.

$$\% = \frac{\text{Conc. (ng/}\mu\text{L)} \times (1 \mu\text{g}/1000\text{ng}) \times (1 \text{ mg}/1000 \mu\text{g}) \times (1000 \mu\text{L}/\text{mL}) \times \text{DF} \times \text{FV} \times 100\%}{\text{Sample Weight (mg)}}$$

where DF=100 is dilution factor used in the dilution the stock solution from 2000 ng/µL to 20 ng/µL, FV=10mL is the final volume of the stock solution. The mean concentration (X) was then calculated for each analyte for the five lots of bifenthrin TGAI.

Precision of the analytical method was determined for each analyte by analyzing seven

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replicate injections of sample solutions prepared from a bifenthrin TGAI sample. The mean (\bar{X}), standard deviation (S) and coefficient of variation (CV) were then calculated for each analyte over the seven replicate analyses.

$$\bar{X} = \frac{\sum X_i}{N}, \quad S = \left\{ \frac{\sum (X_i - \bar{X})^2}{N - 1} \right\}^{1/2}, \quad CV = \frac{S}{\bar{X}} \times 100\%$$

where X_i represent the individual values for a set of N replicate measurements ($N=7$).

Accuracy of the analytical method was demonstrated by analysis of a five-point calibration curve. The percent deviation of the calculated amount, based on the five-point linear regression curve, from the theoretical amount was calculated for bifenthrin for the five-point calibration curve.

$$\% \text{ Deviation} = \frac{\text{Calc Amt} - \text{Theo Amt}}{\text{Theo Amt}} \times 100 \%$$

where Calc Amt is the calculated concentration base upon the linear regression curve, and Theo Amt is the theoretical concentration of the standard.

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 20, 2006

COURIER DELIVERY

George LaRocca (PM 13)
Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

RE: Ensystex II, Inc. – ENS-100 (EPA Reg. No. 81824-4)
Application for Alternate Source of Supply

Dear Mr. LaRocca,

On behalf of Ensystex II, Inc. we are submitting an application for an alternate source of supply of ENS-100 (EPA Reg. No. 81824-4), a technical product containing bifenthrin as the active ingredient. In support of this application, we submit the following documents:

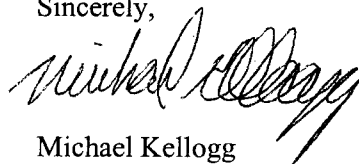
1. Application for Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Letter of Authorization
4. Product Specific Data:

Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Kay, J. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100 (alternate source).
Volume 2	830.1700 and 830.1800	Sun, G. Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient.

Please refer to our original application for registration submitted Nov. 24, 2004 for administrative documents, including the data matrices and labeling. The proposed manufacturing source in this submission is currently unregistered with USEPA. Therefore, Ensystex II believes this submission falls under Fee for Service Category R34 (89: Non fast track amendment) because it involves a change to an unregistered source of active ingredient.

We trust you will find this application complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,



Michael Kellogg

Enclosures

cc: David Nimocks; Ensystex II, Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 81824-4	2. EPA Product Manager G. Larocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ensystex II, Inc. / ENS-100	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Ensystex II, Inc. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 279-3055 Product Name Bifenthrin Technical Insecticide/Miticide	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This submission involves adding a currently unregistered source of active ingredient to the ENS-100 registration. As such, we believe this submission falls under Fee for Service Category R34 (89: Non fast track amendment). The fee due is \$3150 and the decision timeline is 4 months. Please email or fax the fee for service invoice to Fees@PyxisRC.com or 253-853-5516.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) Lined fiber drum	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 25 kg, 50 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Michael Kellogg		Title Agent		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) 15
2. Signature 		3. Title Agent			
4. Typed Name Michael Kellogg		5. Date 2/20/06			

ENSYSTEX II, Inc.

2709 Breezewood Ave., P. O. Box 2587, Fayetteville, NC 28302-2587
Telephone - 1-910-484-6163 x 203 Fax - 1-910-484-3378

August 18, 2004

To Whom It May Concern:

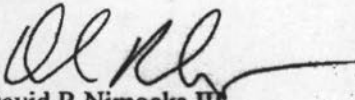
Re Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Ensystex II, Inc. (EPA Company Number pending), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

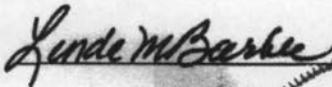
Sincerely,


David R Nimocks III
President

cc: Pyxis Regulatory Consulting, Inc.

State of North Carolina
County of Cumberland

I, Linda Barber, a Notary Public for said County and State, do hereby certify that David R. Nimocks, III personally appeared before me this day, August 18, 2004 and acknowledged the due execution of the foregoing instrument.





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PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
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March 20, 2006

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Arlington, VA 22202

RE: Ensystex II, Inc. – ENS-100 (EPA Reg. No. 81824-4)
Application for Alternate Source of Supply

Dear Mr. LaRocca,

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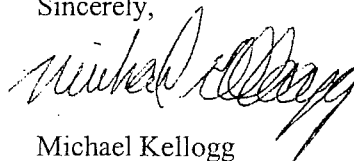
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We trust you will find this application complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,



Michael Kellogg

Enclosures

cc: David Nimocks; Ensystex II, Inc.

ENSYSTEX II, Inc.

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Telephone - 1-910-484-6163 x 203 Fax - 1-910-484-3378

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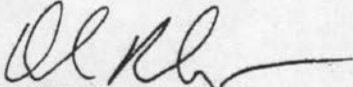
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If you have any questions, please do not hesitate to contact me.

Sincerely,

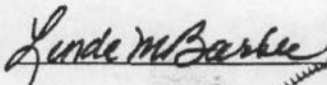


David R Nimocks III
President

cc: Pyxis Regulatory Consulting, Inc.

State of North Carolina
County of Cumberland

I, Linda Barber, a Notary Public for said County and State, do hereby certify that David R. Nimocks, III personally appeared before me this day, August 18, 2004 and acknowledged the due execution of the foregoing instrument.



PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
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March 20, 2006

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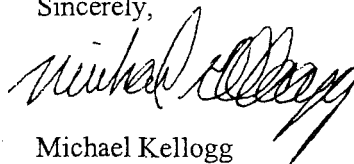
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2. Confidential Statement of Formula (EPA Form 8570-4)
3. Letter of Authorization
4. Product Specific Data:

46788001	Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Kay, J. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100 (alternate source).
46797201	Volume 2	830.1700 and 830.1800	Sun, G. Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient.

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Michael Kellogg

Enclosures

cc: David Nimocks; Ensystex II, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 3, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PYXIS REGULATORY CONSULTING, INC.
ENSYSTEX II, INC.
4110 136TH ST, NW
GIG HARBOR, WA 98332-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 03-APR-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Fee for Service



This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 13

Receipt No.

S- 791880

EPA File Symbol/Reg. No.

81824-4

Pin-Punch Date:

3/21/06

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R-34

Granted: R-34

Amount Due: \$ 3,150⁰⁰

Parent/Child Decisions:

Reviewer: J. Miller

Date: 3-22-06

Remarks:

*Proposes to add alternate formula
with an unregistered source, CSF.
and data on unregistered source included
in package.*

*(BK)
3/22/06*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 28, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-366193
EPA File Symbol or Registration Number: 81824-4
Product Name: ENS-100
EPA Receipt Date: 21-Mar-2006
EPA Company Number: 81824
Company Name: ENSYSTEX II, INC.

Michael Kellogg
PYXIS REGULATORY CONSULTING, INC.
ENSYSTEX II, INC.
4110 136TH ST, NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R34

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS; SOURCE CHANGES TO AN UNREGISTERED SOURCE);

Please remit payment in the amount of: \$ 3,150 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:

U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 23, 2006

PYXIS REGULATORY CONSULTING, INC.
ENSYSTEX II, INC.
4110 136TH ST, NW
GIG HARBOR, WA 98332-

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 21-MAR-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [02]:

- * Judging from the pagination of the study, page 8 was omitted from the submitted copy.

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 20, 2006

COURIER DELIVERY

George LaRocca (PM 13)
Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

RE: Ensystex II, Inc. – ENS-100 (EPA Reg. No. 81824-4)
Application for Alternate Source of Supply

Dear Mr. LaRocca,

On behalf of Ensystex II, Inc. we are submitting an application for an alternate source of supply of ENS-100 (EPA Reg. No. 81824-4), a technical product containing bifenthrin as the active ingredient. In support of this application, we submit the following documents:

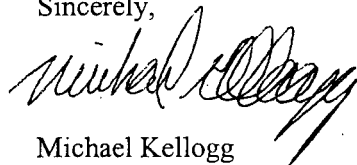
1. Application for Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Letter of Authorization
4. Product Specific Data:

46788001	Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Kay, J. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100 (alternate source).
Reject (02)	Volume 2	830.1700 and 830.1800	Sun, G. Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient.

Please refer to our original application for registration submitted Nov. 24, 2004 for administrative documents, including the data matrices and labeling. The proposed manufacturing source in this submission is currently unregistered with USEPA. Therefore, Ensystex II believes this submission falls under Fee for Service Category R34 (89: Non fast track amendment) because it involves a change to an unregistered source of active ingredient.

We trust you will find this application complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,



Michael Kellogg

Enclosures

cc: David Nimocks; Ensystex II, Inc.

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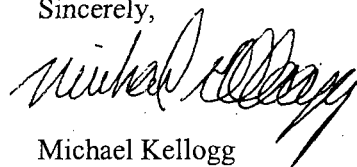
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Michael Kellogg

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 23, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
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PYXIS REGULATORY CONSULTING, INC.
ENSYSTEX II, INC.
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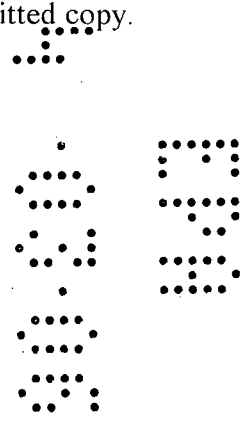
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Pyxis Regulatory Consulting, Inc.

Phone: 253-853-7369

Fax: 253-853-5516

Fax

To: George LaRocca**From:** Janelle Kay**Co.:** RD EPA**Pages:** 2**Fax:** 703-305-6596**Date:** March 31, 2006**Re:** 81824-4 (ENS-100)**CC:**

☐ Urgent ☒ For Review ☐ Please Comment ☐ Please Reply ☐ Confidential

Dear George,

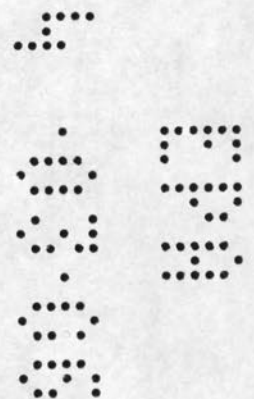
Attached please find the missing page 8 for volume 2. We apologize for any inconvenience this may have caused.

Please do not hesitate to contact me or Mike if you have any questions or need any additional information.

Regards,



Janelle Kay for Michael Kellogg





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**Office of Pesticide Programs
Registration Division (7505C)**

INSECTICIDE BRANCH

F a x

**Name: Michael Kellogg
Organization: Pyxix Regulatory Consulting
Fax Number: 253-853-5516
Phone Number:**

**From: George T. LaRocca,
Product Manager (13)
Phone Number: 703/305-6100
Fax Number: 703/305-6596**

Date: March 31, 2006

Subject: ENS-100 /EPA Reg No. 81821-4

Cover plus 2 Pages:

Comments: See attached letter regarding missing page and resubmit(fax). Thanks.

